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National
Voluntary
Laboratory
Accreditation
Program

# Chemical Calibration

# Certifiers of Spectrophotometric NTRMs

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Stanley D. Rasberry

NIST HANDBOOK 150-21

U.S. Department of Commerce
Technology Administration
National Institute of Standards
and Technology

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NO.150-21
2000

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[1] At Boulder, CO 80303.
[2] Some elements at Boulder, CO.

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February 2000

**U.S. Department of Commerce**
William M. Daley, Secretary

Technology Administration
Cheryl L. Shavers, Under Secretary for Technology

National Institute of Standards and Technology
Raymond G. Kammer, Director

National Institute of Standards and Technology
NIST Handbook 150–21
66 pages (February 2000)
CODEN: NIHAE2

U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON: 2000

For sale by the Superintendent of Documents
U.S. Government Printing Office
Washington, DC 20402-9325

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# PREFACE

The National Institute of Standards and Technology (NIST) operates the National Voluntary Laboratory Accreditation Program (NVLAP®) as a means to accredit laboratories that are competent to conduct specific laboratory functions. While the program does not guarantee the individual results of any given laboratory operation, it does assure users that an accredited laboratory has been assessed and found capable of conducting work to the extent listed in its scope of accreditation.

NIST Handbook 150-21 presents the additional technical requirements of NVLAP for accreditation of laboratories that design, prepare, characterize, certify, and distribute NIST-traceable reference materials (NTRMs™) for spectrophotometric filters. NIST Special Publication SP 260-140 defines an NTRM as a "commercially produced reference material with a well-defined traceability linkage to existing NIST chemical measurement standards." The program may be referred to by the short title "filter NTRMs™." This handbook is intended for information and use by staff of accredited laboratories, those laboratories seeking accreditation, other laboratory accreditation systems, laboratory assessors, users of laboratory services, and others needing information on the accreditation requirements.

This publication supplements NIST Handbook 150, *NVLAP Procedures and General Requirements* (which contains all general NVLAP procedures, criteria, and policies). The criteria in NIST Handbook 150 encompass the requirements of ISO/IEC Guide 25:1990 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987). The provisions of NIST Handbook 150 shall remain in effect for this accreditation program, including the form they may take whenever amended.

The numbering of the sections of NIST Handbook 150-21 is patterned after NIST Handbook 150; for example, Section 285.3 of Handbook 150 presents the description and goal of NVLAP, whereas Section 285.3 of Handbook 150-21 presents the description of the filter NTRMs accreditation program. Where there is no material specific to this accreditation program, the section number is omitted and does not appear in this handbook.

Technical specifications for use by laboratories that design, prepare, characterize, certify, and distribute spectrophotometric filter NTRMs are found in the NIST Special Publications (SP) 260 series. The SP 260 specific to each type of NTRM is listed in Appendix E. Each SP 260 and the present document will be reviewed periodically and revised as necessary to accommodate new technology and revised protocols. Whenever possible, changes to operational procedures will be implemented at the anniversary of an accreditation.

NTRM™ is a trademark of the National Institute of Standards and Technology. It can be applied to certified reference material filters only by certifiers who are accredited under this program. Assessment for accreditation will be administered by NVLAP of NIST, while proficiency evaluation and examination for traceability of certifier measurements to NIST measurements will be conducted by the Analytical Chemistry Division (ACD) of NIST. The ACD will provide technical oversight for this program and will be the sole authority for determining which laboratories meet the technical requirements to be certifiers of NTRMs™. NVLAP will be the sole authority for granting accreditation to laboratories. Accreditation will be granted only after all administrative and technical requirements have been met.

Any questions or comments on this handbook should be submitted to the National Institute of Standards and Technology/NVLAP, 100 Bureau Drive, Stop 2140, Gaithersburg, MD 20899-2140; phone: (301) 975-4016; fax: (301) 926-2884; e-mail: nvlap@nist.gov.

# ACKNOWLEDGMENTS

Thanks are extended to Vanda R. White, whose editorial efforts helped to bring this handbook to fruition. Thanks are also due to all those who contributed to the contents of this handbook.

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# SUMMARY

Any laboratory (including commercial, manufacturer, university, or federal, state, or local government laboratory) that designs, prepares, characterizes, certifies, and distributes spectrophotometric filters may apply to NVLAP for accreditation. The names of NVLAP-accredited laboratories are published in the NVLAP annual directory and other media to which information is regularly provided.

NVLAP grants accreditation to laboratories found compliant to all administrative, quality system, and technical requirements. Technical oversight for this program will be provided by the Analytical Chemistry Division (ACD) of NIST. The ACD will have sole authority for determining which laboratories meet the technical requirements to be certifiers of NTRMs™. NVLAP will administer the accreditation program, and perform laboratory assessments with the advice and assistance of technical assessors from the ACD. Proficiency evaluation will be conducted by the ACD.

*Test methods covered:* The spectrophotometric testing methods covered include those documented and validated by NIST and provided in a NIST SP 260, by the certifier, and, as appropriate, by consensus standards bodies in the areas of material sampling, material preparation and packaging, and spectrophotometric measurement. Test methods are carried out at a level of proficiency commensurate to a laboratory's issuing certified reference materials of high quality.

*Period of accreditation:* Accreditation is for one year, renewable annually.

*On-site assessment:* A visit by an assessor, or more usually a team of assessors, will determine compliance with the NVLAP criteria before initial accreditation and every two years thereafter. Additional monitoring visits may be required if continued compliance comes into question.

*Assessors:* The assessors are technical experts with experience appropriate to evaluating laboratories that perform measurements at a level of quality suitable to the certification of filter NTRMs. The assessment team will include a quality system expert to evaluate the certifier's documented quality system.

*Proficiency evaluation:* Each certifier of filter NTRMs to be accredited is required to participate in proficiency evaluation as described in Appendix D of this handbook. Periodically, a summary of results is sent to the participants.

*Granting accreditation:* Accreditation will be granted by NVLAP to a laboratory that satisfactorily fulfills the conditions for accreditation defined in NIST Handbook 150, *NVLAP Procedures and General Requirements*, the requirements defined in this handbook (including those detailed in the checklists presented in its appendices), and the requirements found in the appropriate NIST SP 260 document. These conditions include satisfactory performance in selected proficiency testing as required, and fulfilling on-site assessment requirements, including resolution of any identified deficiencies. A Certificate and Scope of Accreditation are issued to each successful applicant.

*Fees:* (1) Payments are required as listed on the NVLAP fee schedule and include the administrative/technical support fee, initial application fee, and on-site assessment fee. (2) Payments for laboratory proficiency evaluation and quality assurance monitoring are required as listed by the Analytical Chemistry Division of NIST.

**Sec. 285.1 Purpose**

The purpose of this handbook is to set out procedures and technical requirements for accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP) of laboratories which design, prepare, characterize, certify, and distribute spectrophotometric filter reference materials traceable to the National Institute of Standards and Technology (NIST). The reference materials produced under this program are recognized by NIST as NIST Traceable Reference Materials™, or NTRMs™. They may also be referred to as *filter NTRMs* to differentiate them from other types of NTRMs™.

The standards and specifications used by the certifiers are those published by NIST in the NIST SP 260 series of publications, by consensus standards organizations, and where appropriate, by the certifier, in the areas of material sampling, material preparation and packaging, spectrophotometric characterization, uncertainty analysis, certification, storage, and distribution.

Initially, accreditation will be offered to certifiers of filters used for the measurement of light absorption in the visible spectrum. The range of material certifications to be covered by this program may ultimately be expanded to include other spectral regions or certification of other properties such as markers for calibration of wavelength. See Appendix E for the current list.

Certifiers wishing to become accredited must comply with the requirements of Section 285.33, *Criteria for accreditation*, of NIST Handbook 150, as well as the requirements set forth in this document (NIST Handbook 150-21) and the technical requirements of the relevant NIST SP 260 series document. The quality system requirements contained in NIST Handbook 150 are designed to comply with the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002. The interpretive comments and additional requirements contained in Handbook 150-21 make the general NVLAP criteria specifically applicable to the Certifiers of Spectrophotometric NTRMs program.

**Sec. 285.2 Organization of procedures**

(a) This handbook is organized to cross-reference with NIST Handbook 150, *NVLAP Procedures and General Requirements*. The format and subject headings, including the checklist found in Appendix B, are consistent with Handbook 150.

(b) The handbook contains five appendices:

(1) Appendix A provides examples of a Certificate of Accreditation and a Scope of Accreditation for the Certifiers of Spectrophotometric NTRMs program;

(2) Appendix B provides the General Operations Checklist, which NVLAP assessors use during an on-site assessment to evaluate a certifier's ability to meet filter NTRM production requirements in general;

(3) Appendix C provides the Specific Operations Checklist, which NVLAP assessors use during an on-site assessment to evaluate performance in preparing, characterizing, certifying, and distributing filter NTRMs;

(4) Appendix D lists the procedures that NIST will use for testing the proficiency of certifiers; and,

(5) Appendix E lists the range of filter characteristics available for inclusion in a scope of accreditation.

**Sec. 285.3 Description of the Certifiers of Spectrophotometric NTRMs program**

This program provides accreditation to those laboratories that can demonstrate their capabilities and competence as certifiers of spectrophotometric filter reference materials that meet the technical specifications and requirements as published. See NIST SP 260-140, *Technical Specifications for Certification of Spectrophotometric NTRMs*. Laboratories that have received NVLAP accreditation are permitted to distribute, with the designation NTRM™, filter reference materials that they have designed, prepared, characterized, and certified, and that meet all the technical specifications and other requirements set forth in this program.

To achieve and maintain accreditation, laboratories must demonstrate their competence by periodically participating in proficiency testing. The required proficiency testing programs will be operated by the NIST ACD on a cost recovery basis.

To be accredited under the program described in this handbook, certifiers of spectrophotometric filter NTRMs must undergo periodic on-site assessment of their quality system and competence. Also, periodically they must demonstrate their proficiency

in accurately characterizing the filter materials they distribute. The procedures for conducting these assessments and demonstrations are found in this handbook.

**Sec. 285.4 References**

References and sources for the Certifiers of Spectrophotometric NTRMs program follow:

**(a)** The following documents are referenced in this handbook:

**(1)** NIST Handbook 150, *NVLAP Procedures and General Requirements* (March 1994).

**(2)** NIST Special Publication SP 260-140, *Technical Specifications for Certification of Spectrophotometric NTRMs,* 1999.

**(3)** NIST Technical Note 1297, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, 1994 Edition.

**(4)** ANSI/NCSL Z540-2-1997, *U.S. Guide to the Expression of Uncertainty in Measurement*, 1997.

**(5)** ISO Guide 30, *Terms and definitions used in connection with reference materials*, 1992.

**(6)** ISO Guide 31, *Contents of certificates of reference materials*, 1981 (under revision).

**(7)** ISO Guide 34, *Quality system guidelines for the production of reference materials*, 1996.

**(8)** ISO Guide 35, *Certification of reference materials - General and statistical principles*, 1989.

**(9)** ISO/IEC/BIPM, *International Vocabulary of Basic and General Terms in Metrology*, 2nd ed., 1993.

**(b)** Sources for the above-referenced documents follow:

**(1)** The NIST documents listed as items **(a)(1)** through **(a)(3)** are available from:

NIST/NVLAP
100 Bureau Drive, Stop 2140
Gaithersburg, MD 20899-2140

Phone: (301) 975-4016
Fax: (301) 926-2884
E-mail: nvlap@nist.gov

**(2)** ANSI/NCSL Z540-2-1997 (item **(a)(4)**) may be ordered from:

National Conference of Standards Laboratories (NCSL)
1800 30th Street, Suite 305B
Boulder, CO 80301-1032

Phone: (303) 440-3339
Fax: (303) 440-3384
E-mail: ncsl-staff@ncsl-hq.org

**(3)** The ISO documents listed as items **(a)(5)** through **(a)(9)** are available from:

American National Standards Institute
11 West 42 Street, 13th Floor
New York, NY 10036

Phone: (212) 642-4900
Web site: www.ansi.org

**Sec. 285.5 Definitions** (additional to those found in Handbook 150)

**Accuracy of measurement:** Closeness of the agreement between the result of a measurement and a true value of the measureand. [*International Vocabulary of Basic and General Terms in Metrology* (VIM), 3.5]

**Assigned value:** Value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose. [See VIM, 1.20.] Assigned value is formally named "conventional true value (of a quantity)" in the VIM.

**Certifiers of Spectrophotometric NTRMs; for short, "Certifiers":** Laboratories that design, prepare, characterize, certify and distribute NTRM filter reference materials.

**Proficiency test (PT):** A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through measurement and reporting of results on unknown materials provided by an external provider of proficiency testing (NIST) or by NIST's examining materials and certified measurements provided by the laboratory under test.

**Standard Reference Material® (SRM®):** A reference material certified and distributed by the National Institute of Standards and Technology (NIST).

**Sec. 285.6 NVLAP documentation**

The technical requirements for certifying NTRMs of spectrophotometric filters are found in appropriate NIST SP 260s.

Assessment checklists contain definitive statements or questions about all aspects of the NVLAP criteria for accreditation. They will be used together with the technical requirements found in the appropriate NIST SP 260 to examine all aspects of a laboratory's qualifications to be a certifier of filter NTRMs. NVLAP programs incorporate two types of checklists:

**(a)** The NVLAP General Operations Checklist addresses factors applicable to evaluating a certifier's ability to operate a technical laboratory in accordance with the procedures and general requirements for accreditation. The factors include, but are not limited to, the certifier's organization, management, and quality system in addition to its technical competency.

The General Operations Checklist, presented in Appendix B, is numbered to correspond to the requirements in NIST Handbook 150. The comment sheets are used by the assessor to explain findings and deficiencies noted on the checklist, as well as to make comments on aspects of the certifier's performance other than deficiencies.

**(b)** The Specific Operations Checklist contains statements or questions that are specific to the Certifiers of Spectrophotometric NTRMs program. This checklist is contained in Appendix C, along with comment sheets similar to those used with the General Operations Checklist.

**Sec. 285.22 Assessing and evaluating a certifier**

**(a) On-Site Assessment**

**(1)** The applicant certifier will provide the NVLAP lead assessor with manuals and/or documented procedures in advance of the on-site assessment to reduce the time spent on-site. Documents supplied in advance will be returned. The certifier should be prepared for conducting demonstrations of spectrophotometric measurement, have equipment in good working order, and be ready for examination according to the technical specifications found in the NIST SP 260, and the requirements identified in this handbook, NIST Handbook 150, and the certifier's quality manual. The assessor will need time and work space to complete assessment documentation during the visit.

**(2)** The checklists found in Appendices B and C, together with the technical specifications found in the appropriate NIST SP 260, will be used by the assessor, or assessment team, to help assure the completeness, objectivity, and uniformity of the on-site assessment. The assessment will include a review of the certifier's ability to perform appropriate measurement and testing procedures. The review may range from observing tests to having laboratory staff describe or demonstrate the procedures. The assessor notes the depth into which each part of the operational procedure was reviewed and records the results of the review on the specific operations checklist comment sheet.

**(3)** An assessor or assessment team performs the following activities during a typical on-site assessment:

**(i)** Conducts, under the direction of the lead assessor, an entry briefing with the Authorized Representative or his/her designee to explain the purpose of the on-site visit and to discuss the schedule for the day(s). At the discretion of the Authorized Representative, other staff members may attend the briefing.

(ii) Reviews certifier records and documents. At least one certifier staff member must be available to answer questions; however, an assessor may wish to review documents alone.

**(iii)** Physically examines equipment and facilities, observes the demonstration of selected procedures by appropriate personnel, and interviews the personnel. The demonstrations requested may be selective or all-inclusive and must include sampling of material(s), preparation and packaging of materials, setup/use of major equipment, establishment of test conditions, and the technical aspects of

conducting spectrophotometric measurements on filters of the type normally certified by the laboratory. Such technical aspects shall include, but not be limited to: the design of measurement procedures, calibration and validation of instruments, data collection, data evaluation methodology, results reporting, and assurance of correct match of results to materials.

(iv) Completes an On-Site Assessment Report, covering at a minimum the requirements prescribed in NIST Handbook 150, and including copies of all completed checklists.

(v) Conducts an exit briefing to discuss the team's findings, including all deficiencies and comments. The On-Site Assessment Report is signed by the lead assessor and the certifier's Authorized Representative to acknowledge the discussion. Signing does not necessarily indicate agreement and challenge(s) may be made through NVLAP. All observations made by NVLAP assessors are held in the strictest confidence.

**(b) Proficiency Testing**

**(1)** The proficiency testing program for evaluation of certifiers of spectrophotometric NTRMs will be conducted by the Analytical Chemistry Division (ACD) of the National Institute of Standards and Technology. The tests will be conducted according to the specifications found in the appropriate NIST SP 260 and the provisions of Appendix D of this handbook, and with the support of the NIST Statistical Engineering Division.

**(2)** Proficiency testing will follow one or both of two models, as required by the ACD and as described in Appendix D of this handbook. The two models are briefly described as follows:

(i) ***Direct Proficiency Testing.*** In this model, filters will be sent by NIST ACD to certifiers of spectrophotometric NTRMs as unknowns for measurement. After completion of the measurements, each certifier will return its results to NIST ACD for evaluation of the certifier's proficiency.

(ii) ***Indirect Proficiency Testing.*** In this model, each certifier of filter NTRMs will submit to NIST ACD a portion of each lot of material produced. NIST ACD can then judge the proficiency of the certifier by checking the validity of the certifier's claims regarding assigned values.

**Sec. 285.23 Granting and renewing accreditation**

Certifiers granted NVLAP accreditation receive two documents: a Certificate of Accreditation and a Scope of Accreditation. Samples of these accreditation documents for the Certifiers of Spectrophotometric NTRMs program are shown in Appendix A. Note that the certificate states that the criteria encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987).

**Sec. 285.33 Criteria for accreditation**

**(a) Scope**

(See NIST Handbook 150.)

**(b) Organization and management**

(See NIST Handbook 150.)

**(c) Quality system, audit and review**

**(1)** The certifier shall define and document its quality procedures for obtaining accurate and precise measurement data and for conducting its operations as a certifier of filter NTRMs, in accordance with the technical specifications set forth in the appropriate NIST SP 260. These procedures shall be the benchmarks by which certifier management assesses overall and individual performance.

**(2)** Under its quality system, the certifier shall develop and implement procedures covering all the technical requirements of this handbook and the NIST SP 260. Professional staff shall be able to obtain enough information from the certifier's quality documentation to perform their work in the absence of the manager. Periodic management reviews of the quality system shall reflect adherence to NVLAP requirements and the certifier's quality procedures. These reviews shall reflect positive

aspects of the quality system as well as deficiencies.

(3) The quality manual shall describe the certifier's staff, facilities and equipment, test procedures, calibration procedures, material custody and handling procedures and test report format and procedures. The quality system documentation shall also contain:

(i) specific records (or reference to records) of material preparation, packaging and storage locations;

(ii) provisions for routine quality assurance checks to verify overall methodology;

(iii) procedures for calibration of equipment;

(iv) procedures for measurement and certification of filters;

(v) filled-in examples of all standardized forms, including computerized forms and formats, used by the certifier; and

(vi) procedures for storage and retrieval of records.

(4) The certifier's quality assurance checks shall be performed routinely, covering all time periods, material types, instruments, tasks and personnel. Where appropriate, the specific checks on personnel performance shall be executed without the prior knowledge of the personnel being checked. Quality assurance activities shall not be postponed during periods of heavy work loads.

(5) The certifier shall conduct and summarize quality assurance activities on a frequent enough basis to detect problems.

(6) Laboratories seeking accreditation under the Certifiers of Spectrophotometric NTRMs program shall have available a copy of all references listed under Sec. 285.4 of this handbook.

(d) **Personnel**

(1) Employees shall be aware of the extent of their area of responsibility. This information shall be available in the required job descriptions found in the quality documentation and individual files.

(2) The certifier shall have a written description of its training program including its criteria for successful completion. The certifier shall establish and document performance criteria to determine when a new technical staff member is qualified for working independently.

(3) Technical staff members shall participate in an appropriate form of continuing education which may include formal course work, in-house education, and scientific or technical meetings, and have access to journals or reprints that describe advances in the fields of spectrophotometric measurement and optical testing of filters.

(4) Technical staff member competence is important to providing reliable data. All technical staff members shall be tested routinely to evaluate their performance. Test results shall be recorded in the personnel folder or equivalent of each staff member and be available during NVLAP on-site assessments. Testing shall be frequent enough to ensure quality measurements. Problems shall be discussed with the technical staff member and corrected according to documented procedures.

(5) Follow-up quality assurance tests shall determine whether staff performance problems have been corrected. The certifier shall ensure the quality of measurements while the problems are being corrected. All corrective actions shall be documented in quality assurance summaries, periodic laboratory audits, and individual technical staff member's files.

(6) The certifier shall be organized so that staff members are not subjected to undue pressure or inducement that might influence their judgment or results of their work. The certifier shall be able to demonstrate that work loads are consistent with provision of high-quality spectrophotometric filter NTRMs.

(7) The certifier will be responsible for demonstrating its competence to measure filters

following the practice outlined in its quality documentation. Staff members involved in the measurement of filters will be responsible for demonstrating their competence as required during an on-site assessment.

**(e) Accommodation and environment**

(See NIST Handbook 150 and the appropriate NIST SP 260 document.)

**(f) Equipment and reference materials**

**(1)** All equipment including a "transfer spectrophotometer" (see NIST SP 260-140, 2.2.1) shall be properly maintained to ensure protection from contamination, corrosion and other forms of deterioration. Instructions for proper maintenance of equipment must be available. Any equipment or component thereof that has been subjected to contamination or critical mishandling, gives suspect results, or has been shown to be defective, must be taken out of service and clearly labeled until it has been repaired. When placed back in service, this equipment must be demonstrated as performing its functions satisfactorily.

**(2)** The certifier shall have the reference materials and any associated certificates used in evaluation of personnel and calibration of equipment. At a minimum this will include one current set of SRMs 930, 1930, and 2034.

**(3)** The certifier shall maintain procedures for ensuring and documenting that automated test systems function properly and are used properly.

**(4)** The algorithms contained in any measurement-related software will be known and have demonstrated validity and applicability for their intended use.

**(g) Measurement traceability and calibration**

**(1)** Calibrations or validation may be performed by properly trained staff using calibrated standards, including Standard Reference Materials, that are traceable to NIST or by using a laboratory accredited by NVLAP or by an accrediting body recognized by NVLAP through a Mutual Recognition Arrangement (hereinafter referred to as *appropriately accredited*). All calibrations and characterizations must be done against reference standards that are traceable to national standards maintained by NIST or by a foreign national measurements institute, recognized by NIST, that issues reference or calibration materials. It is the responsibility of the certifier seeking accreditation to determine that, where appropriate, calibration services use reference standards traceable to NIST or to a recognized foreign national standards authority.

**(2)** Certificates, records, and evidence of the traceability of the reference standards used must be retained and made available for an assessor's inspection during the on-site visit. The certificates must indicate certified values and uncertainties and traceability of reference standards. If calibration or validation is performed by the certifier, the standard metrological procedures used, the environmental conditions, and the measurement uncertainty must be documented. Certificates are required for calibration performed by outside services; they are not required for general purpose testing equipment not directly used for calibration, validation, or filter certification.

**(3)** The records for each calibration or validation measurement shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration, analyzing, or testing.

**(4)** Control charts will be developed in accordance with NIST SP 260-140, 5.4.

**(5)** In addition to the information specified in NIST Handbook 150, Sec. 285.33(f)(4), testing equipment records shall include the following:

**(i)** notation of all equipment variables requiring calibration;

**(ii)** the range of calibration;

**(iii)** as appropriate, the resolution, detection limit, and sensitivity of the instrument and its allowable error;

**(iv)** identity of the person or company responsible for service and calibration of the instrument; and

(v) source of reference standards and traceability.

(h) **Calibration and test methods**

(1) A certifier's laboratories shall use validated methods that are appropriate to the material being certified and that are consistent with the uncertainty criteria that are in place for the given method at the time of the measurement. The certifier must have a copy of all specifications and validated test methods that it uses in the filter NTRM certification programs for which it seeks accreditation.

(2) Testing conducted in the Certifiers of Spectrophotometric NTRMs program may include:

(i) transmittance measurement;

(ii) wavelength measurement;

(iii) stray radiation measurement; and

(iv) optical testing for such properties as flatness, wedge and transmittance uniformity.

(3) The certifier's laboratory shall conform in all respects with the validated method employed to assign a value to a filter NTRM. A certifier will validate each method used by comparison with Standard Reference Materials certified and issued by the National Institute of Standards and Technology, unless appropriate SRMs are not available, or the certifier can show an alternative and convincing demonstration of traceability to national standards.

(4) The certifier shall follow written procedures to address all aspects of producing filter NTRMs (e.g., material preparation and assessment, measurement, certification, packaging, storage, and stability verification, etc.).

(5) Filter measurement and certification shall meet all requirements of the appropriate NIST SP 260 document.

(6) Uncertainties will be assigned according to procedures given in NIST SP 260-140, 2.4.

(i) **Handling of calibration and test items**

(1) The certifier shall follow written procedures covering all aspects of procuring, preparing, handling, and storage of filter NTRM materials.

The log-in system shall include documentation of the date of receipt, unique identification for the material, condition of the material, and the acceptance or rejection of the material. The certifier shall follow written criteria for acceptance or rejection of materials.

(2) The certifier shall have a materials record system that documents the following information:

(i) source of the material;

(ii) location of the material;

(iii) personnel who have handled or worked with the material; and

(iv) what has been done to the material, including rejection of unsuitable material.

The system for identifying filter NTRMs and component source materials must remain in force from the date of procurement of the material to the date of its disposal, either through documents or through marking, to ensure that there is no confusion regarding the identity of the materials and the results of the measurements.

(3) The certifier must be able to demonstrate that all applicable shipping and safety regulations are met.

(4) The mode of shipment and the procedures for shipment must be designed to guard the integrity and stability of the material.

(5) Shipping records must provide adequate information to track custody of the material and to provide for the possibility of recall, if necessary.

**(j) Records (also see Specific Operations Checklist)**

**(1)** Measurement data shall be developed, maintained and transmitted to NIST in accordance with NIST SP 260-140, 5.7.

**(2)** Records may be kept in hard copy form and must be available in the computer format specified in the appropriate NIST SP 260 document (with an adequate back-up system.) They shall be readily accessible to authorized users and secure from unauthorized users.

**(3)** The period of retention shall be 3 years, unless a longer period is required by the client, regulation, or the certifier's own procedures. Records of certification data will be retained for the life of each certified filter.

**(4)** Procedures for storage and retrieval of records shall be documented and maintained in the certifier's quality system documentation. Records shall be stored in a logical fashion allowing retrieval within one working day.

**(k) Certificates and reports**

**(1)** Certificates and reports accompanying filter NTRMs will conform to NIST Handbook 150 and ISO Guide 31.

**(2)** Information supplementary to the certificates may be provided as instructions or reports. Such documents shall be clearly labeled as to their purpose and as to which specific individual filter NTRM they accompany.

**(3)** Certificates, instructions and reports must be provided in such manner that it is clear that they are to remain with the filter NTRMs through all stages of shipment and handling, until they have reached the personnel who are to use them.

**(l) Subcontracting**

**(1)** Whenever a laboratory performs work as a certifier of filter NTRMs, it is required that the work is performed, results obtained, and the reports prepared by the personnel, equipment, and procedures of that certifier at that site. However, in some cases a certifier may require the use of another facility due to equipment failure, need for specialized equipment, work overload, or to perform tests outside the certifier's own scope of accreditation.

**(2)** Whenever a certifier subcontracts to a laboratory the performance of any work, test, or portion of a test associated with the production and certification of filter NTRMs it must:

**(i)** place the work with a laboratory that is appropriately accredited for the specific work to be done;

**(ii)** document, as part of the information and instructions provided to clients, the extent of that subcontracting; and

**(iii)** clearly identify in its records, and in all reports to the clients, specifically which test method(s) or portions of a test method(s) were performed in-house and which were performed by the subcontractor.

**(m) Outside support services and supplies**

(See NIST Handbook 150.)

**(n) Complaints**

(See NIST Handbook 150.)

# APPENDIX A

# SAMPLE ACCREDITATION DOCUMENTS

United States Department of Commerce
National Institute of Standards and Technology

NVLAP®

ISO/IEC GUIDE 25:1990
ANSI/NCSL Z540-1-1994
ISO 9002:1987

## Certificate of Accreditation

DEPARTMENT OF COMMERCE ★ UNITED STATES OF AMERICA ★

**LABORATORY NAME**
ANYTOWN, USA

*is recognized under the National Voluntary Laboratory Accreditation Program for satisfactory compliance with criteria established in Title 15, Part 285 Code of Federal Regulations. These criteria encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987) as suppliers of calibration or test results. Accreditation is awarded for specific services, listed on the Scope of Accreditation for:*

**CHEMICAL CALIBRATION: CERTIFIERS OF SPECTROPHOTOMETRIC NTRMS**

March 31, xxxx
*Effective through*

David F. Alderman
*For the National Institute of Standards and Technology*

NVLAP-02C (11-95)

NVLAP LAB CODE: 000000-0

National Institute of Standards and Technology

NVLAP®

National Voluntary Laboratory Accreditation Program

ISO/IEC GUIDE 25:1990
ANSI/NCSL Z540-1-1994
ISO 9002:1987

# Scope of Accreditation

DEPARTMENT OF COMMERCE
UNITED STATES OF AMERICA

**CHEMICAL CALIBRATION:**
**CERTIFIERS OF SPECTROPHOTOMETRIC NTRMS**

**NVLAP LAB CODE 000000-0**


**LABORATORY NAME**
Street Address
Anytown, USA 00000-0000
Mr. John Doe
Phone: 000-000-0000 Fax: ###-###-####


| *NVLAP Code* | *Designation* | *Range* |
|---|---|---|
| 20/N01 | Visible Absorbance | 1% T to 50% T |

March 31, xxxx

*Effective through*

David F. Alderman

*For the National Institute of Standards and Technology*

NVLAP-02S (11-95)

# APPENDIX B

# GENERAL OPERATIONS CHECKLIST

NVLAP LAB CODE: _____

# GENERAL OPERATIONS CHECKLIST

**Instructions to the Assessor:** This checklist addresses general accreditation criteria prescribed in applicable sections of NIST Handbook 150, *NVLAP Procedures and General Requirements*.

This checklist follows and is numbered to correspond to the *NVLAP Procedures and General Requirements*, Subsection 285.33. The numbers in square brackets identify related checklist items. A small black triangle appears in the left-hand margin of selected lines of text throughout this checklist; the marked text applies only to the Calibration Laboratory Accreditation Program (LAP).

Place an "X" beside each checklist item which represents a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and your written deficiency explanations and/or comments in this list or on the attached comment sheets. Place a check beside all other items you observed or verified at the laboratory.

## SEC. 285.33 CRITERIA FOR ACCREDITATION

(b) ***Organization and management***

(1) The laboratory shall be:

_____ (i) legally identifiable;

Legal name of laboratory ownership: _____

(ii) organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the NVLAP requirements [see also (b)(2)(i), (c)(2)(ii)];

_____ (iii) properly identified on the NVLAP Application.

(2) The laboratory shall:

_____ (i) have managerial staff with the authority and resources needed to discharge their duties [see also (b)(1)(ii), (c)(2)(ii)];

_____ (ii) have policies to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

_____ (iii) be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times;

_____ (iv) specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

_____ (v) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test, and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

_____ (vi) have a technical manager (however named) who has overall responsibility for the technical operations;

Name of person: _____

_____ (vii) have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

Name of person: _____

_____ (viii) nominate deputy(ies) in case of absence of the technical or quality manager;

Name(s): _____

_____ (ix) have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights [see also (c)(2)(xviii)];

_____ (x) where appropriate, participate in interlaboratory comparisons and proficiency testing programs [see also (c)(2)(xiv), (c)(6)(ii), (g)(3)];

_____ (xi) have documented policy and procedures to ensure that its clients are served with impartiality and integrity.

(c) ***Quality system, audit and review***

(1) The laboratory shall:

_____ (i) have an established and maintained quality system appropriate to the type, range and volume of calibration and testing activities it undertakes;

_____ (ii) have the elements of the quality system documented;

_____ (iii) ensure that the quality documentation is available for use by the laboratory personnel;

_____ (iv) define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services;

_____ (v) have the laboratory management which ensures that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned;

_____ (vi) ensure that the quality manual is maintained current under the responsibility of the quality manager [see also (c)(2)(iv)].

Date of quality manual: _____

Date of latest update: _____

(2) The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the NVLAP requirements. The quality manual and related quality documentation shall contain:

_____ (i) a quality policy statement, including objectives and commitments, by top management;

_____ (ii) the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

_____ (iii) the relations between management, technical operations, support services and the quality system;

_____ (iv) procedures for control and maintenance of documentation [see also (c)(1)(vi), (j)(1)];

_____ (v) job descriptions of key staff and reference to the job descriptions of other staff;

_____ (vi) identification of the laboratory's approved signatories (list here or in the comments section): _____

_____

_____ (vii) the laboratory's procedures for achieving traceability of measurements;

_____ (viii) the laboratory's scope of calibrations and/or tests;

_____ (ix) written procedures for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

_____ (x) reference to the calibration, verification and/or test procedures used;

_____ (xi) procedures for handling calibration and test items;

_____ (xii) reference to the major equipment and reference measurement standards used;

_____ (xiii) reference to procedures for calibration, verification and maintenance of equipment;

_____ (xiv) reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes [see also (b)(2)(x), (c)(6)(ii), (g)(3)];

(xv) procedures to be followed for feedback and corrective action whenever:

_____ a) testing discrepancies are detected, or

_____ b) departures from documented policies and procedures occur;

_____ (xvi) the laboratory management policies for departures from documented policies and procedures or from standard specifications;

_____ (xvii) procedures for dealing with complaints [see also (n)];

_____ (xviii) procedures for protecting confidentiality and proprietary rights [see also (b)(2)(ix)];

_____ (xix) procedures for audit and review;

_____ (xx) a description of the laboratory's policy regarding the use of the NVLAP logo;

▸ _____ (xxi) a statement of the laboratory's policy for establishing and changing
▸ calibration intervals for equipment it controls; and

_____ (xxii) a statement of the laboratory's policy concerning the technique(s) to be used for determining measurement uncertainty and calibration/verification adequacy.

_____ (3) The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

The audits shall be objective and be conducted internally or on contract. The audits shall include both general criteria (documents, records and policies) and technical compliance (test methods and practices and calibration procedures).

_____ (4) The quality system adopted to satisfy the NVLAP requirements shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

_____ (5) All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

(6) In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

_____ (i) internal quality control plans, such as control charts and other available statistical techniques;

**NOTE:** Measurement assurance techniques are acceptable means to control the measurement process and consistently produce the highest quality measurements.

_____ (ii) participation in proficiency testing or other interlaboratory comparisons [see also (b)(2)(x), (c)(2)(xiv), (g)(3)];

_____ (iii) regular use of certified reference materials and/or in-house quality control using secondary reference materials;

_____ (iv) replicate testings using the same or different methods;

_____ (v) retesting of retained items;

_____ (vi) correlation of results for different characteristics of an item.

(d) ***Personnel*** [see also (c)(2)(v)]

_____ (1) The testing laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

_____ (2) The testing laboratory shall ensure that the training of its personnel is kept up-to-date.

_____ (3) Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

(e) ***Accommodation (facilities) and environment*** [see also (i)(3)]

_____ (1) Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

**NOTE:** Laboratory design will be, to the maximum extent practical, in accordance with the guidelines found in the NCSL Recommended Practice #7, *Laboratory Design*, July 25, 1993.

_____ (2) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

**NOTE:** It is expected that environments which do not meet generally accepted norms, such as those found in NCSL Recommended Practice #7, yet which exhibit the stability required to apply necessary correction factors, will be specified by the laboratory for the purpose of assessment of compliance with its own procedures to achieve its stated uncertainties.

_____ (3) The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

_____ (4) There shall be effective separation between neighboring areas when the activities therein are incompatible.

_____ (5) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

_____ (6) Adequate measures shall be taken to ensure good housekeeping in the laboratory.

**NOTE:** While it is the laboratory's responsibility to comply with relevant health and safety requirements, this is outside the scope of this assessment.

(f) ***Equipment and reference materials***

(1) The laboratory shall:

_____ (i) be furnished with all items of equipment (including hardware, software, and reference materials) required for the correct performance of calibrations and tests;

_____ (ii) in those cases where the laboratory needs to use equipment outside its permanent control, including rented, leased and client-owned equipment, ensure that the relevant NVLAP requirements are met.

_____ (2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

_____ (3) Each item of equipment including reference materials shall, when appropriate, be labelled, marked or otherwise identified to indicate its calibration status.

_____ (4) Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:

_____ (i) the name of the item of equipment, software or reference material;

_____ (ii) the manufacturer's name, type identification, and serial number or other unique identification;

_____ (iii) date received and date placed in service;

**NOTE:** For initial accreditation, the date received and the date placed in service are not considered mandatory requirements for inclusion in laboratory records, although this is encouraged as good laboratory practice.

_____ (iv) current location, where appropriate;

_____ (v) condition when received (e.g., new, used, reconditioned);

_____ (vi) copy of the manufacturer's instructions, where available;

_____ (vii) dates and results of calibrations and/or verifications and date of next calibration and/or verification;

_____ (viii) details of maintenance carried out to date and planned for the future;

_____ (ix) history of any damage, malfunction, modification or repair;

► _____ (x) measured value observed for each parameter found to be out of tolerance during calibration/verification.

(g) ***Measurement traceability and calibration***

_____ (1) All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. The program will ensure the recall or removal from service of any standard or equipment which has exceeded its calibration interval or is otherwise judged to be unreliable.

_____ (2) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall, wherever applicable, indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

**NOTE:** Traceability to national standards includes traceability to standards maintained or defined at national laboratories in foreign countries where applicable. In these cases, traceability is achieved via international standards. This includes intrinsic standards of measurement where available.

Where applicable, the methodology of the *Guide to the expression of uncertainty in measurement*: 1993, shall be used as the basis for expression of uncertainty of the measurement. NIST Technical Note 1297; January 1993, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, is a practical application document written around the *Guide to the expression of uncertainty in measurement*. Where detailed procedures are not used to quantify and combine uncertainties (i.e., use of test accuracy ratio concepts), the sources of uncertainty shall be tabulated and demonstrated to be acceptable for the measurement undertaken.

**NOTE:** A significant number of intrinsic standards, such as the Josephson Array Voltage Standard and the Iodine-Stabilized Helium-Neon Laser Length Standard, have been developed and are now being used by many national standards laboratories and some industrial laboratories. These standards are based on well-characterized laws of physics, fundamental constants of nature, or invariant properties of materials, and make ideal stable, precise, and accurate measurement standards if properly designed, characterized, operated, monitored and maintained. Where intrinsic standards are used, the laboratory should demonstrate by measurement assurance techniques, interlaboratory comparisons, or other suitable means, that its intrinsic standard measurement results are correlated with those of national or international standards.

_____ (3) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing [see also (b)(2)(x), (c)(2)(xiv), (c)(6)(ii)].

**NOTE:** Traceability requirements may also be satisfied by:

(i) internationally accepted standards in the field concerned;

(ii) suitable reference materials;

(iii) ratio or reciprocity measurements; or

(iv) mutual consent standards which are clearly specified and mutually agreed upon by all parties concerned.

_____ (4) Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

_____ (5) Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.

_____ (6) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

_____ (7) Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

**(h)** ***Calibration and test methods***

_____ (1) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

_____ (2) The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

**NOTES:**

(i) Calibration procedures shall contain the required range and tolerance or uncertainty of each item or unit parameter being calibrated or verified. In addition, the procedures shall contain the generic description of the measurement standards and equipment needed with the required parameter, range, tolerances or uncertainties, and specifications for performing the measurement of the calibration or verification, and/or representative types (manufacturer, model, option) that are capable of meeting the generic description for the measurement standards. The procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations/verifications concerned.

(ii) The laboratory shall ensure that the calibration uncertainties are sufficiently small so that the adequacy of the measurement is not affected. Well-defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of a measurement process. If such techniques are not used, then the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance (e.g., manufacturer's specification) for each characteristic of the measuring and test equipment being calibrated or verified.

_____ (3) Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

_____ (4) Where it is necessary to employ methods that have not been established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports [see also (k)(2)(x)].

_____ (5) Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples [see also (k)(2)(ix)].

_____ (6) Calculations and data transfers shall be subject to appropriate checks.

(7) Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall have written procedures which ensure that:

_____ (i) the NVLAP requirements are complied with;

_____ (ii) computer software, computers or automated equipment is documented and adequate for use;

_____ (iii) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

_____ (iv) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data [see also (f)(1)];

_____ (v) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

_____ (8) Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory [see also (m)(2)].

(i) ***Handling of calibration and test items***

_____ (1) The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time [see also (k)(2)(v)].

_____ (2) Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

_____ (3) The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned [see also (e)].

_____ (4) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

_____ (5) Tamper-resistant seals shall be affixed to operator-accessible controls or adjustments on measurement standards or measuring and test equipment which, if moved, will invalidate the calibration. The laboratory's calibration system shall provide instructions for the use of such seals and for the disposition of equipment with damaged or broken seals.

**NOTE:** Tamper-resistant seals are sometimes affixed to equipment to prevent unauthorized access to areas where adjustments or critical components are located.

(j) ***Records***

_____ (1) The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing [see also (c)(2)(iv)].

▸ **EXCEPTION:** The retention of all original observations, calculations, and
▸ derived data in the calibration record system is not a mandatory requirement
▸ for calibration laboratories, although it is encouraged as good laboratory
▸ practice.

_____ (2) All records (including those listed in (f)(4) pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client [see also (b)(2)(ix), (c)(2)(xviii)].

**NOTE:** The period of retention shall be specified in the quality manual.

Record retention time specified: _____

(k) *Certificates and reports*

_____ (1) The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used [see also (k)(4)].

▸ **NOTE:** It is recognized that the results of each calibration do not always
▸ result in the production of a calibration certificate or report. Whenever a
▸ certificate or report is produced, the above requirements shall be met.

(2) Each certificate or report shall include at least the following information:

_____ (i) a title, e.g., "Calibration Certificate," "Test Report" or "Test Certificate";

_____ (ii) name and address of laboratory, and location where the calibration or test was carried out if different from the address of the laboratory;

_____ (iii) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

_____ (iv) name and address of client, where appropriate;

_____ (v) description and unambiguous identification of the item calibrated or tested [see also (i)(1)];

_____ (vi) characterization and condition of the calibration or test item;

_____ (vii) date of receipt of calibration or test item and date(s) of performance of calibration or test, where appropriate;

▸ **EXCEPTION:** Although it is encouraged as good laboratory practice, the
▸ requirement for inclusion of the date received is not mandatory for calibration
▸ laboratories.

_____ (viii) identification of the calibration or test method used, or unambiguous description of any non-standard method used;

_____ (ix) reference to sampling procedure, where relevant [see also (h)(5)];

_____ (x) any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to a specific calibration or test, such as environmental conditions [see also (c)(2)(xv), (h)(4)];

_____ (xi) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;

_____ (xii) a statement of the estimated uncertainty of the calibration or test result, where relevant;

_____ (xiii) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue [see also (c)(2)(vi)];

_____ (xiv) where relevant, a statement to the effect that the results relate only to the items calibrated or tested;

_____ (xv) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;

_____ (xvi) a statement that the report must not be used by the client to claim product endorsement by NVLAP or any agency of the U.S. Government;

_____ (xvii) the signature of an approved signatory for all test and calibration reports endorsed with the NVLAP logo;

▸ _____ (xviii) special limitations of use; and

▸ _____ (xix) traceability statement.

_____ (3) Where the certificate or report contains results of calibrations or tests performed by subcontractors, these results shall be clearly identified [see also (l)].

_____ (4) Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible [see also (k)(1)].

_____ (5) Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate (or Test Report or Test Certificate), serial number ... (or as otherwise identified)," or equivalent form of wording. Such amendments shall meet all the relevant requirements of item (j).

_____ (6) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report, or test certificate or amendment to a report or certificate.

**NOTE:** Such notification shall quantify the magnitude of error created in the calibration results. The laboratory shall notify customers promptly, in writing, of any customer's measuring and test equipment found significantly out of tolerance during the calibration/verification process. Measurement data shall be reported so that appropriate action can be taken.

_____ (7) The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the NVLAP requirements are met and that confidentiality is preserved.

_____ (8) Whenever a laboratory accredited by NVLAP issues a calibration or test report which contains data covered by the accreditation and also data not covered by the accreditation, it must clearly identify in its records, and in the report to the client, specifically which calibration or test method(s), or portion of a calibration or test method(s), was not covered by the accreditation. The laboratory must also inform the client, before the fact, when calibrations or tests requested are not covered by the accreditation.

NVLAP policy regarding calibration and test reports issued by an accredited laboratory, which reference the laboratory's accredited status, requires that any calibration or test report containing data from calibrations or tests which are not covered by the accreditation include:

_____ (i) a statement at the beginning of the report prominently indicating, "This report contains data which are not covered by the NVLAP accreditation"; and

_____ (ii) a clear indication of which data are not covered by the accreditation.

The laboratory must not misrepresent its accreditation. When a client requires or requests accredited services and any of the requested services are not covered by the accreditation, the client must be so advised.

(l) ***Subcontracting of calibration or testing*** [see also (k)(3)]

_____ (1) Where a laboratory subcontracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being subcontracted. The laboratory shall advise the client in writing of its intention to subcontract any portion of the testing to another party.

_____ (2) The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all subcontracting.

_____ (3) A NVLAP-accredited laboratory intending to subcontract testing or calibration work that will be performed and reported as meeting NVLAP procedures and criteria must:

_____ (i) have in its quality manual a subcontracting policy compatible with the NVLAP policy, with a description of the procedures for administering and implementing those actions to demonstrate the conformance and consistency of the subcontracted laboratory to perform according to NVLAP procedures;

_____ (ii) place the subcontracted work with a laboratory that maintains accreditation established by NVLAP shown by a current NVLAP Lab Code, or provide and maintain current records that demonstrate that the subcontracted laboratory is competent to perform the test(s) or calibration(s) and that it operates in a manner consistent with and in conformance to NVLAP criteria for accreditation;

_____ (iii) clearly identify in its records, and in the report to the client, exactly which data were obtained by the NVLAP-accredited laboratory and which data were obtained by the subcontractor, NVLAP-accredited or not;

_____ (iv) inform its client, before the fact, that it intends to subcontract for completion of all or a portion of the client's work; and

_____ (v) include at the beginning of the report the name, address, and contact person of the subcontracted laboratory(ies), and one of the following statements, as appropriate:

*if NVLAP-accredited*

"This report contains data which were produced by a subcontracted laboratory **ACCREDITED (NVLAP LAB CODE)** for the calibration or test methods performed"

*if not NVLAP-accredited*

"This report contains data which were produced by a subcontracted laboratory **NOT ACCREDITED** for the calibration or test methods performed."

The requirements of this section do not supersede any regulation, law, contract specification, or other related conditions which require NVLAP accreditation.

(m) ***Outside support services and supplies***

_____ (1) Where the laboratory procures outside services and supplies in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

_____ (2) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned [see also (h)(8)].

_____ (3) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

(n) ***Complaints*** [see also (c)(2)(xvii)]

_____ (1) The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

_____ (2) Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the NVLAP requirements or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with item (c)(3).

(o) ***Measuring and test equipment (M & TE)***

**NOTE:** This section applies to the control of measuring and test equipment (M & TE) used to assure that supplies and services comply with prescribed customer requirements. It is based in large part on the requirements found in government audit standards such as MIL-STD 45662A, and is found in Part II of the ANSI/NCSL Z540-1-1994 (Draft) standard.

(1) General requirements for M & TE

_____ (i) The supplier shall establish and document a system to control the calibration/verification of M & TE.

_____ (ii) M & TE used to determine compliance with customer technical specifications shall be calibrated or verified in accordance with sections 285.33(b) through (n).

_____ (iii) The supplier shall have a program to recall for calibration or verification, or remove from service, M & TE that has exceeded its calibration interval, has broken calibration seals, or is suspected to be malfunctioning because of mishandling, misuse, or unusual results.

_____ (iv) All operations performed by the supplier in compliance with these requirements shall be subject to customer verification at unscheduled intervals.

_____ (v) The supplier shall carry out, or arrange to have carried out, periodic quality auditing of the calibration and verification system in order to ensure its continuing effective implementation and compliance with these requirements.

- Based on the results of the audits and any other relevant factors, such as customer feedback, the supplier shall review and modify the system as necessary.

- Plans and procedures for the audits shall be documented. The conduct of the audit and any subsequent corrective action shall also be documented.

(2) Detailed requirements for M & TE

_____ (i) Calibration system description: The supplier shall provide and maintain a written description of the calibration/verification system covering M & TE and measurement standards. The description shall be sufficient to satisfy each requirement of section 285.33(o) and any deviations shall be submitted with supporting documentation to the customer for approval.

_____ (ii) Adequacy of measurement standards: Measurement standards used by the supplier for calibrating M & TE and other measurement standards shall comply with the requirements of items (f)(1), (g)(1), and (h)(2).

_____ (iii) Environmental conditions: M & TE shall be used in an environment controlled to the extent necessary to ensure valid results. Due consideration shall be given to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference and any other factors affecting the results of measurements. Where pertinent, these factors shall be monitored and recorded and, when appropriate, correcting compensations shall be applied to measurement results.

_____ (iv) Intervals of calibration and verification: M & TE requiring calibration shall be calibrated or verified at periodic intervals established and maintained to assure acceptable reliability, where reliability is defined as the probability that M & TE will remain in-tolerance throughout the interval. Intervals shall be established for all M & TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process. Check standards must closely represent the item parameters normally tested in the process and the check standard must be verified periodically. Where intervals are used to ensure reliability, the interval setting system must be systematically applied and shall have stated reliability goals and a method of verifying that the goals are being attained. Intervals may be based on usage or time since last calibration or verification. All exemptions from periodic calibration or verification shall be documented. The recall system may provide for the temporary extension of the calibration due date for limited periods of time under specified conditions that do not unreasonably impair the satisfaction of the customer's requirements.

_____ (v) Calibration procedures: Procedures used to calibrate/verify the supplier's M & TE shall comply with the requirements of items (h)(1) and (h)(2).

_____ (vi) Out-of-tolerance conditions: If any M & TE is found to be significantly out of tolerance during the calibration/verification process, the supplier's system shall provide for notification to the user and to the supplier's quality element, if appropriate, of the out-of-tolerance condition with the associated measurement data so that appropriate action can be taken.

_____ (vii) Adequacy of calibration system: The supplier shall establish and maintain documented procedures to evaluate the adequacy of the calibration system and to ensure compliance with these requirements.

_____ (viii) Calibration sources: M & TE requiring calibration shall be calibrated or verified by laboratories that comply with sections 285.33(b) through (n).

_____ (ix) Records: These requirements shall be supported by records documenting that established schedules and procedures are followed to maintain the adequacy of all M & TE. The records for M & TE requiring calibration shall include an individual record of calibration or verification, or other means of control, providing a description or identification of the item, calibration interval, date calibrated, identification of the calibration source, calibration results (data and/or condition status) and calibration action taken (adjusted, repaired, new value assigned, derated, etc.).

_____ (x) Calibration status: M & TE shall be labeled to indicate calibration or verification status. The label shall identify specific date calibrated (day, month, year, Julian date, or equivalent) and the specific calibration due date or usage equivalent. Items not calibrated to their full capability or which have other limitations of use, shall be labeled or otherwise identified as to the limitations. When it is impractical to apply a label directly to an item, the label may be affixed to the instrument container or some other suitable means may be used to reflect calibration status. Tamper-resistant seals are affixed to operator accessible controls or adjustments which if moved will invalidate the calibration. The quality system shall provide instructions for the disposition of equipment with broken tamper-resistant seals.

_____ (xi) Control of subcontractor calibration: The supplier is responsible for assuring that the subcontractor's calibration system conforms to section 285.33 (l) to the degree necessary to assure compliance with contractual requirements. NVLAP accreditation of the subcontractor's laboratory can serve as the basis for compliance with this requirement.

_____ (xii) Storage and handling: M & TE shall be handled, stored, and transported in a manner which shall not adversely affect the calibration or condition of the equipment.

NVLAP LAB CODE: [ ]

## GENERAL OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

**Instructions to the Assessor:** Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

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# APPENDIX C

# SPECIFIC OPERATIONS CHECKLIST

NVLAP LAB CODE: _____

## CHEMICAL CALIBRATION: CERTIFIERS OF SPECTROPHOTOMETRIC NTRMS SPECIFIC OPERATIONS CHECKLIST

**Instructions to the Assessor:** This checklist addresses specific accreditation criteria prescribed in applicable sections of NIST Handbook 150-21.

Place an "X" beside any of the checklist items which represent a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and your written deficiency explanations and/or comments on this list or on the comment sheet(s). Place a check beside all other items you observed or verified at the certifier's facility.

### 1 Organization and management

(See General Operations Checklist.)

### 2 Quality system, audit and review

_____ 2.1 The laboratory has the current edition of the following documents available for reference:

_____ 2.1.1 NIST Handbook 150, *NVLAP Procedures and General Requirements*;

_____ 2.1.2 NIST Handbook 150-21, *NVLAP Certifiers of Spectrophotometric NTRMs*;

_____ 2.1.3 NIST Special Publication SP 260-140, *Technical Specifications for Certification of Spectrophotometric NTRMs*;

_____ 2.1.4 ANSI/NCSL Z540-2-1997, *U.S. Guide to the Expression of Uncertainty in Measurement*, 1997; or NIST Technical Note 1297, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, 1994 edition;

_____ 2.1.5 ISO Guide 31, *Contents of certificates of reference materials*;

_____ 2.1.6 ISO Guide 34, *Quality system guidelines for the production of reference materials*; and,

_____ 2.1.7 ISO Guide 35, *Certification of reference materials – General and statistical principles*.

_____ 2.2 The laboratory's quality documentation contains procedures or instructions describing the following:

_____ 2.2.1 training of staff and quality assurance of technical staff member performance;

_____ 2.2.2 material custody and handling procedures;

_____ 2.2.3 facility maintenance, and equipment maintenance, calibration and verification as a certifier of filter NTRMs, in accordance with the technical specifications set forth in the appropriate NIST SP 260;

_____ 2.2.4 data processing for measurements and generation of certificates; and

_____ 2.2.5 back-up and security of data and reports.

_____ 2.3 The laboratory conducts an internal audit not less than annually to verify that its operations are in compliance with its quality manual and this program.

_____ 2.4 The laboratory participates in proficiency testing established by NIST. (See Appendix D of NIST Handbook 150-21.)

_____ 2.5 The laboratory quality documentation shall include all the technical requirements of NIST Handbook 150-21 and the appropriate NIST SP 260 document.

**3 Personnel**

_____ 3.1 The laboratory ensures that staff members are aware of the extent of their area of responsibility.

_____ 3.2 The laboratory maintains documentation for each staff member as follows:

_____ 3.2.1 staff member's title and description of that job position;

_____ 3.2.2 job and quality assurance responsibilities;

_____ 3.2.3 résumé;

_____ 3.2.4 training;

_____ 3.2.5 assigned laboratory procedures and duties; and

_____ 3.2.6 results of periodic testing performance reviews.

_____ 3.3 The laboratory has a description of its staff training program including its criteria for successful completion.

_____ 3.4 Technical staff members and technical supervisors participate in some form of continuing education, such as formal course work, in-house education, and technical

meetings, and have access to journals and other information that describe advances in the field.

_____ 3.5 The laboratory has available for the assessor results of its staff testing program.

_____ 3.6 Laboratory schedules indicate that time pressures do not detract from staff performance.

**4 Accommodation (facilities) and environment**

_____ 4.1 The certifier maintains a facility that:

_____ 4.1.1 provides a safe work environment for all employees;

_____ 4.1.2 permits safe handling of chemicals used for any purpose; and,

_____ 4.1.3 prevents contamination or degradation of proficiency test materials and of the raw materials from which they are prepared.

_____ 4.2 Laboratory space where filter NTRMs are tested and measured meets the following minimum requirements:

_____ 4.2.1 ventilation and lighting suitable to the tasks conducted;

_____ 4.2.2 class 100,000 particle containment;

_____ 4.2.3 temperature between 20 °C and 22 °C;

_____ 4.2.4 humidity 70% or lower; and

_____ 4.2.5 access limited to trained staff.

**5 Equipment and reference materials**

_____ 5.1 The certifier can demonstrate that equipment is properly maintained.

_____ 5.2 A "transfer spectrophotometer" has been "qualified" per NIST SP 260-140, 2.2.1.

_____ 5.3 Appropriate Standard Reference Materials from NIST are available for use, together with the certificates that accompany the SRMs. At a minimum this includes one current set each of SRMs 930, 1930, and 2034.

_____ 5.4 SRMs are properly stored and used according to the instructions that accompany them.

_____ 5.5 Procedures are available for validating any automated test systems. Currently used versions of operating systems, and measurement and data reduction software are validated and documented.

_____ 5.6 The algorithms contained in any measurement related software are known and have demonstrated validity and applicability.

**6 Measurement traceability and calibration**

_____ 6.1 Calibrations or verifications, including maintenance of control charts, are performed by properly trained staff using standard reference materials traceable to NIST, when available.

_____ 6.2 The transfer spectrophotometer is verified weekly against SRMs from NIST and the data are archived in hard copy and electronic form. Control charts will be available for assessor review.

_____ 6.3 Wavelength calibration is verified and archived monthly by means of a full spectrum scan of SRM 2034.

_____ 6.4 NTRM certifier standards are maintained in accordance with NIST SP 260-140, 5.3.

_____ 6.5 Reference materials are stored according to the instructions given on their certificates and guarded from degradation and contamination during storage and use. Care is given to verifying that the correct certificate is available for each reference material and that the expiration date given on the certificate for the material has not passed.

_____ 6.6 Testing equipment records indicate calibration requirements, ranges, allowable error, and staff member(s) responsible for the required calibrations.

**7 Calibration and test methods**

_____ 7.1 Copies are available of all uncertainty criteria, specifications, and validated test methods employed in the certification of filter NTRMs.

_____ 7.2 The certifier can demonstrate conformance to all filter cleaning, calibration and testing requirements set forth in the technical specifications for producing filter NTRMs (appropriate NIST SP 260s.)

_____ 7.3 The certifier follows written procedures regarding critical aspects of filter NTRM production, including:

_____ 7.3.1 material preparation;

_____ 7.3.2 verification of surface flatness, opposite face parallelism, and transmittance uniformity according to NIST SP 260-140, 2.2.2;

_____ 7.3.3 nominal transmittance conformance;

_____ 7.3.4 material measurement and certification, meeting all requirements of the appropriate NIST SP 260 document, with certificates being in conformance with NIST Handbook 150 and ISO Guide 31;

_____ 7.3.5 material storage;

_____ 7.3.6 verification of stability;

_____ 7.3.7 assignment of uncertainties according to NIST SP 260-140, 2.4; and,

_____ 7.3.8 recertification of filter NTRMs.

## 8 Handling of calibration and test items

_____ 8.1 The laboratory has a material log system used to identify filter NTRM materials and their components uniquely, and to document the source, processing, storage, and use of the materials. The log includes:

_____ 8.1.1 the source and date of receipt of the material;

_____ 8.1.2 the condition of the material;

_____ 8.1.3 documentation of acceptance or rejection of material, including reasons in any case of rejection;

_____ 8.1.4 a unique laboratory identification number for each material and for each test sample, thereof (having all coding and marking in accordance with NIST SP 260-140, 3.4); and,

_____ 8.1.5 the initials of the person making the above entries in the material log book.

_____ 8.2 Where there is any doubt as to the material's suitability for use (e.g., a mismatch between identification and description), the laboratory has a procedure for resolving the problem. Such action is documented and all out-of-tolerance filters are rejected.

_____ 8.3 The laboratory can demonstrate that proper shipping procedures are employed including:

_____ 8.3.1 adherence to all applicable shipping and safety regulations;

_____ 8.3.2 provision of material safety data sheets, where applicable;

_____ 8.3.3 assurance that shipment mode does not comprise filter NTRM stability; and,

_____ 8.3.4 the ability to track custody of material, in the event a recall is needed.

## 9 Records

_____ 9.1 The laboratory's quality system documentation follows written procedures for the storage and retrieval of records.

_____ 9.2 Records are stored in a logical fashion allowing retrieval within one working day.

_____ 9.3 The laboratory has documentation, either electronic backup or "paper" hard copy, to assure survival of original data if computer systems are used for primary data retention.

_____ 9.4 The laboratory ensures that the technical staff member signs (or initials) and dates the original data.

_____ 9.5 The following records are maintained for a minimum of 3 years:

_____ 9.5.1 materials log;

_____ 9.5.2 original data collected by technical staff member(s);

_____ 9.5.3 identity of personnel involved in material preparation and measurement;

_____ 9.5.4 measurement data accompanied by its metadata as required in NIST SP 260-140, 5.7;

_____ 9.5.5 quality control activities and results including spectrophotometer calibration and control of environmental factors in accordance with NIST SP 260-140, 4.2 and 5.4 (Control Charts);

_____ 9.5.6 filter NTRM test results and summary reports;

_____ 9.5.7 equipment and maintenance;

_____ 9.5.8 certification reports (noting that certification data for each filter must be retained for the life of the filter);

_____ 9.5.9 recertification documentation, filter condition, and recertification data; and,

_____ 9.5.10 records of all actions taken in response to customer complaints.

_____ 9.6 The certifier provides, in electronic format, data to NIST in accordance with NIST SP 260-140, 4.6 and 5.7.

_____ 9.7 Filled-in examples are available for all standardized forms and reports.

**10 Certificates and Reports**

_____ 10.1 Certificates accompanying filter NTRMs are found to be in conformance with ISO Guide 31.

_____ 10.2 Any necessary supplementary information is clearly labeled and described.

_____ 10.3 Clear instructions are given that certificates and associated documentation are to be available to the personnel who use the filter NTRMs.

**11 Subcontracting of calibration or testing**

(See General Operations Checklist.)

**12 Outside support services and supplies**

(See General Operations Checklist.)

**13 Complaints**

(See General Operations Checklist.)

NVLAP LAB CODE: _____

## SPECIFIC OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

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# APPENDIX D

# PROCEDURES FOR TESTING THE PROFICIENCY OF CERTIFIERS

# PROCEDURES FOR TESTING THE PROFICIENCY OF CERTIFIERS

## A. Direct Proficiency Testing

**(1)** The direct proficiency testing program will be conducted by the National Institute of Standards and Technology (NIST). The work will be carried out by the Analytical Chemistry Division (ACD) of the Chemical Science and Technology Laboratory, with the support of the Statistical Engineering Division of the Information Technology Laboratory. Proficiency testing materials are chosen to test the certifier's ability to follow a method and to achieve results at or exceeding the required level of accuracy found in the appropriate NIST SP 260.

**(2)** Certifiers will be sent test materials, data sheets, and instructions for performing the test and reporting the results. The test shall be conducted in accordance with a specific test method using specified standard operating procedures. Proficiency testing shall not be contracted out to another laboratory. Any special NIST/ACD instructions shall also be followed. The special instructions are designed to ensure uniformity in procedures among participants. Completed data shall be returned to NIST/ACD, in electronic format, for review by a specified date. Failure to return the proficiency testing data by the deadline equals failure to participate. See paragraph (10).

**(3)** On occasion, the on-site assessor may hand carry proficiency test materials to the certifier. These proficiency test materials, like all others measured by the laboratory, are to be listed or entered into the laboratory's normal material tracking and identification system for control and data recording. In these cases, the samples may be returned to the on-site assessor rather than stored at the laboratory.

**(4)** The results of the proficiency testing program will be reported to the participants and in appropriate documents and reports. The identity and performance of individual certifiers will remain confidential. The results of proficiency testing will be made available to on-site assessors for use during laboratory visits. Any problems indicated by proficiency testing will be discussed with appropriate laboratory personnel, who will then be responsible for developing and implementing plans for resolving the problems. Accreditation decisions will be based in part on satisfactory resolution of proficiency testing deficiencies.

**(5)** A proficiency test will use statistical and graphical techniques to examine the performance of each certifier based on the results obtained on test materials provided by NIST/ACD. If a laboratory exceeds the critical limit for the test sample it will fail the proficiency test.

Submitted results that are incomplete or that fall outside the critical limits will be considered as failing.

**(6)** If an accredited certifier fails a proficiency test, it must do the following to maintain its accreditation:

> **(i)** Within 30 days of notification of failure, provide to NVLAP detailed, written documentation that includes an analysis of why the laboratory failed any part of the test, and what corrective actions it has taken (technical staff member training, revised procedures, quality assurance activities, etc.) to resolve its measurement problems so as to avoid similar errors in the future. Documented evidence that the corrective actions have been effectively implemented is required.

**(ii)** Participate successfully in the next round of proficiency testing.

**(7)** If a certifier fails the same type of proficiency testing twice in succession or generally exhibits an erratic pattern in testing, NVLAP will review all current and previous proficiency testing results and advise the certifier on what actions must be taken to correct the deficiency. Failure to correct the deficiency may result in suspension of accreditation.

**(8)** To regain lost accreditation, the certifier may be required to undergo a complete on-site reassessment to determine the cause of the deficiencies and to determine that effective corrective actions have been implemented. The certifier shall provide NVLAP with documentation within 30 days of the reassessment, adequately demonstrating that any deficiencies noted by the assessor have been satisfactorily resolved. Failure to perform fully satisfactorily in the on-site reassessment will result in accreditation remaining suspended.

**(9)** The full cost of any on-site reassessment shall be paid in advance by the certifier. NVLAP staff will make every effort to expedite these extraordinary assessments to give a certifier every reasonable opportunity to demonstrate competence to perform the test method and regain accreditation.

**(10)** Failure to participate in a round of proficiency testing will result in immediate suspension of accreditation, and the certifier shall successfully participate in the next regularly scheduled round to have its accreditation reinstated.

## B. Indirect Proficiency Testing

**(1)** The indirect proficiency testing program will be conducted by the National Institute of Standards and Technology (NIST). The work will be carried out by the Analytical Chemistry Division (ACD) of the Chemical Science and Technology Laboratory, with the support of the Statistical Engineering Division of the Information Technology Laboratory. Competence of the certifier will be tested based on materials and certificates produced by that certifier.

**(2)** For every lot of filter NTRMs issued by a certifier, the certifier will send to NIST/ACD, a unit, or units, of the filter NTRM together with certificates and additional pertinent documents, such as instructions and shipping documents. Initially, a certifier will be required to provide to NIST/ACD one test unit from each group of 30 certified filter NTRM units. The proportion of test units to be provided to NIST/ACD will be reconsidered at each renewal of accreditation and adjusted as necessary. Additionally, NIST/ACD may obtain specimens of a specific certifier's output through purchase, or by loan from a third party who has purchased the material. These last two options are intended to provide NIST with the possibility of making "blind," unannounced tests of filter quality.

**(3)** As part of its evaluation of the certifier's competence, NIST may measure the submitted material or otherwise use the material in any way it deems useful.

**(4)** Whenever a filter NTRM is recalibrated, recalibration data will be made available electronically to NIST/ACD for use in assessment of long-term material stability. The data obtained by NIST/ACD will be considered, within the technical limits of accounting for user treatment of the filters, in judging the certifiers proficiency in distributing filter NTRMs of suitable stability. Decisions regarding certifier proficiency with respect to stability will be based

on broad patterns of success or failure—not individual instances related to one or a few filter NTRM units.

**(5)** The results of the proficiency testing program will be reported to the participants and in appropriate documents and reports. The identity and performance of individual certifiers will remain confidential. The results of proficiency testing will be made available to on-site assessors for use during visits to the certifier. Any problems indicated by proficiency testing will be discussed with appropriate certifier personnel, who will then be responsible for developing and implementing plans for resolving the problems. Accreditation decisions will be based in part on satisfactory resolution of proficiency testing deficiencies.

**(6)** Testing by NIST/ACD may take either of two forms:

**(i)** A material submitted, with assigned values and standard deviations, by a certifier may be measured by NIST/ACD, with the results being compared to the values and standard deviations assigned by the certifier being examined.

**(ii)** A material submitted as in (6) (i), above, may be held for future measurement pending the outcome of customer experience using filter NTRMs from the given lot, or pending review of filter NTRM recertification data collected on specimens from the given lot. The material may be tested later, at the discretion of NIST/ACD. It will be tested in the event anomalous results arise in the use of a specific lot of filter NTRMs.

**(7)** If an accredited certifier fails an indirect proficiency test, it must do the following to maintain its accreditation:

**(i)** Within 30 days of notification of failure, provide to NVLAP detailed, written documentation that includes an analysis of why the certifier failed each part of the test, and what corrective actions it has taken (technical staff member training, revised procedures, quality assurance activities, etc.) to resolve its measurement problems so as to avoid similar errors in the future. Documented evidence that the corrective actions have been effectively implemented is required.

**(ii)** Participate successfully in indirect proficiency testing at the time the certifier certifies its next lot of filter NTRMs.

**(8)** If a certifier fails an indirect proficiency test twice in succession or generally exhibits an erratic pattern in testing, NVLAP will review all current and previous proficiency testing results and advise the certifier on what actions must be taken to correct the deficiency. Failure to correct the deficiency may result in suspension of accreditation.

**(9)** To regain lost accreditation, the certifier may be required to undergo a complete on-site reassessment to determine the cause of the deficiencies, and to determine that effective corrective actions have been implemented. The certifier shall provide NVLAP with documentation within 30 days of the reassessment, adequately demonstrating that any deficiencies noted by the assessor have been satisfactorily resolved. Failure to perform fully satisfactorily in the on-site reassessment will result in accreditation remaining suspended.

**(10)** The full cost of any on-site reassessment shall be paid in advance by the certifier. NVLAP staff will make every effort to expedite these extraordinary assessments to give a certifier every

reasonable opportunity to demonstrate competence to perform the test method and regain accreditation.

**(11)** Failure to submit the agreed upon filter NTRM unit from each production lot, together with the assigned values, and standard deviations for each certified characteristic will result in immediate suspension of accreditation, and the certifier shall successfully participate in the next regularly scheduled round to have its accreditation reinstated.

# APPENDIX E

# NTRMS AVAILABLE FOR INCLUSION IN A SCOPE OF ACCREDITATION

NVLAP LAB CODE: _____

## CHEMICAL CALIBRATION: CERTIFIERS OF SPECTROPHOTOMETRIC NTRMS PROGRAM SELECTION LIST

**Instructions:** Check each program for which you are requesting accreditation.

| | *NVLAP Code* | *Program Designation* | *Technical Specifications* |
|---|---|---|---|
| _____ | 20/N01 | Visible Absorbance | NIST SP 260-140 |

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